



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018-0320; FRL-11655-01-OCSPP]

### Toxic Substances Control Act Review of CBI Claims for the Identity of Chemicals in the TSCA Inventory; Extension of Review Period

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This document announces the extension of the review period for Confidential Business Information (CBI) claims for specific identify of all active chemical substances listed on the confidential portion of the Toxic Substances Control Act (TSCA) Inventory submitted to the EPA under TSCA. EPA has determined that an extension of the statutory review period for the review of CBI claims under TSCA are necessary to allow the Agency to complete the required reviews under TSCA.

**DATES:** The review period is extended to February 19, 2025.

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0320, is available online at <http://www.regulations.gov>. Additional instructions for visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Jessica Barkas, Project Management and Operations Division (7401), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 250-8880; email address: [barkas.jessica@epa.gov](mailto:barkas.jessica@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

**SUPPLEMENTARY INFORMATION:**

## **I. Does this action apply to me?**

You may be affected by this action if you submitted a Notice of Activity Form A to EPA under TSCA section 8(b)(4) and 40 CFR part 710, subpart B and asserted any CBI claims concerning the specific identities of the chemical substances you reported. Persons who seek information on such submissions may also be affected by this action. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Manufacturers, importers, or processors of chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

If you have any questions regarding the applicability of this action to a particular entity, consult the technical contact person listed under **FOR FURTHER INFORMATION CONTACT**.

## **II. What is the Agency's authority for taking this action?**

TSCA authorizes the extension of the Review Plan deadline in TSCA section 8(b)(4)(E)(ii)(I), 15 U.S.C. 2607(b)(4)(E)(ii)(I).

## **III. What action is the Agency taking?**

EPA is announcing to the public that it is extending an Agency review deadline pursuant to the authority in TSCA section 8(b)(4)(E)(ii)(I), 15 U.S.C. 2607(b)(4)(E)(ii)(I). The additional time is necessary to complete the reviews given the volume of submissions that require review, information technology issues, and other legal and administrative delays that have affected the review process. EPA will evaluate progress toward completing the requirements for the Agency to review CBI substantiations outlined in the final rule entitled “Procedures for Review of CBI Claims for the Identity of Chemicals in the TSCA Inventory” (Review Plan rule), (85 FR 13062, March 6, 2020 (FRL-10005-48)), which set a deadline of February 19, 2024. This action will extend the deadline by a year and as this extended deadline approaches the Agency may further

extend the deadline as necessary to complete the Review Plan reviews.

#### **IV. What is the TSCA Review Plan?**

Pursuant to TSCA section 8(b), EPA finalized the Review Plan rule establishing, *inter alia*, the Agency's plan for reviewing all active TSCA Inventory CBI claims concerning specific chemical identity that had been made in Active-Inactive rule reporting taking place in 2017 and 2018 (see 40 CFR part 710, subparts B (Commercial Activity Notification) and C (Review Plan)). Consistent with TSCA section 8(b)(4)(E)(i), which allows a five-year period for these reviews following compilation of an initial list of active substances, the reviews were targeted for completion by February 19, 2024 (see 40 CFR 710.55(d)). Since finalizing the Review Plan rule, however, EPA has encountered issues that, cumulatively, make reaching this target highly unlikely. Consequently, consistent with TSCA section 8(b)(4)(E)(ii)(I) and 40 CFR 710.55(e) which permit EPA to extend the review period by up to two years, EPA is extending the target review completion date until February 19, 2025. As this extended deadline approaches, EPA will re-evaluate the Review Plan progress and will further extend the deadline, as necessary to complete the Review Plan reviews, up to February 19, 2026.

Several issues and factors caused delays that are expected to prevent EPA from completing its review within the five-year period. Firstly, the volume of claims is significant. EPA received and is reviewing CBI claims for the specific chemical identity of more than 4,805 chemical substances in 5,787 submissions under the Review Plan. At the same time, the Agency is maintaining its CBI review program for new CBI claims under TSCA section 14(g). This involves reviewing numerous and varied types of TSCA submissions, containing a wide array of CBI claims of differing complexity. The Agency receives approximately 600 submissions with multiple CBI claims requiring review under TSCA section 14(g) each year. Also concurrent with these CBI review activities, EPA is processing denied and withdrawn CBI claims for chemical identity so that those chemical identities may be disclosed on the public portion of the TSCA Inventory, consistent with the requirements of TSCA sections 8(b) and 14.

Secondly, adapting the Agency's information technology (IT) systems to complete these reviews has presented issues and contributed to delays as part of processing the voluminous amount of CBI claims. For example, in its reviews, EPA observed duplication of and inconsistencies between confidentiality claims for the same chemicals across and between submissions. Limitations with existing IT tools have made identifying and resolving such issues a largely manual process, which consumes resources and delays Agency reviews. In addition, the size (i.e. very large file size) and other features of certain submissions have caused IT difficulties that have halted the CBI review process for more than six months and these issues have not yet been resolved as available resources have been prioritized to address more critical IT needs.

Finally, EPA could not start its Review Plan reviews until after a delay of approximately six months to a year as a result of the decision of the U.S. Court of Appeals for the District of Columbia Circuit in *Environmental Defense Fund v. EPA*, 922 F.3d 446 (D.C. Cir. 2019). The Court's decision meant that any company who had voluntarily provided substantiation in their initial Notice of Activity filing (mostly made in 2018) had to ensure those prior submissions included information regarding reverse engineering (generally by answering two additional substantiation questions), and that EPA had to provide a reporting period for doing so prior to beginning any Review Plan reviews. EPA published a supplement to the proposed Review Plan rule to address the Court's decision on November 8, 2019 (84 FR 60363 (FRL-10001-44)). The final rule required substantiation or supplemental substantiation by November 2020 (see 40 CFR 710.47). The additional reporting requirement created confusion among some reporting entities, the resolution of which has further slowed the review process.

These issues and factors together justify extending the review period deadline by at least one year, consistent with TSCA section 8(b)(4)(E)(ii)(I).

**Authority:** 15 U.S.C. 2607(b).

Dated: January 18, 2024.

**Michal Freedhoff,**

*Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

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